Area	Guinea Pig Number							
	1		2		3		4	
	Left	Right	Left	Right	Left	Right	Left	Right
C	P_L	P_L	P_H	P_H	S_L	S_L	S_H	S_H
D	P_H	P_H	P_L	P_L	S_H	S_H	S_L	S_L

(d) *Calculation of test results.* Between 40 and 66 hours following injection, a diameter of the reaction for each injection site shall be calculated by averaging two diameters of the reaction measured at right angles to each other. The average reaction for each dilution for each animal shall be determined, then the average diameters of the reactions of all of the guinea pigs for each dilution shall be calculated. The ratios of the reactions are determined by dividing the average diameter of the low dilution of the product under test by the average diameter of the low dilution of the standard and by dividing the average diameter of the high dilution of the product by the average diameter of the high dilution of the standard.

(e) *Potency requirement.* The potency of the product under test is satisfactory if each calculated ratio of the reactions of the product under test and of the standard is 1.0. The potency of the lot under test is considered to be equal to that of the standard if the ratios are not lower than 0.77 or higher than 1.30, provided that in a single test the ratios are substantially the same.

§650.5 Stability test.

A sample of each lot of the product shall be held at 37° C for not less than 24 hours and then tested for potency as prescribed in §650.4. The stability of the product is satisfactory if test results of the sample meet the potency requirement prescribed in §650.4(e).

§650.6 Samples; protocols; official release.

For each lot of the product, the following material shall be submitted to the Director, Center for Biologics Evaluation and Research:

(a) A protocol which consists of a summary of the history of manufacture of each lot including all results of all tests for which test results are requested by the Director, Center for Biologics Evaluation and Research.

(b) A sample of no less than 20 milliliters of the product.

(c) The product shall not be issued by the manufacturer until written notification of official release of the lot is received from the Director, Center for Biologics Evaluation and Research.

[38 FR 32097, Nov. 20, 1973, as amended at 42 FR 27584, May 31, 1977; 49 FR 23834, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

Subpart B—Tuberculin

§650.10 Tuberculin.

The proper name of this product shall be Tuberculin, which shall be a preparation derived from *Mycobacterium tuberculosis* or *M. Bovis.*

§650.11 General requirements.

(a) *General safety.* Each lot of Tuberculin shall be tested for safety as prescribed in §610.11 of this chapter, except that the sample of tuberculin from multiple puncture devices shall be obtained by removing the tuberculin in a manner that will permit the injection of material from at least five devices into each of two guinea pigs and from at least two devices into each of two mice.

(b) *Labeling.* In addition to complying with all other applicable labeling provisions of this subchapter, the package label shall state the following:

(1) For Tuberculin for Mantoux testing, the number of U.S. units (TU) per dose.

(2) For Tuberculin for multiple puncture testing, a statement indicating that the activity per test is comparable to a stated number of U.S. units (TU) administered by the Mantoux method.

(3) The applicable type of Tuberculin placed immediately following and of no less prominence than the proper name, as follows:

(i) ''Old,'' or